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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/907,907	07/16/2001	Paul B. Fisher	A34584-A-PCT-USA-(070050.	1356

7590 08/17/2004

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/907,907

Applicant(s)

FISHER ET AL.

Examiner

David J Blanchard

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22 and 85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 2 and 85 are pending.  
Claims 1-21 and 23-84 have been cancelled.  
Claim 22 has been amended.
2. Claims 2 and 85 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Objections/Rejections Withdrawn***

4. The objections to the specification (parts a-c) are withdrawn in view of the amendments filed 7/15/2004.
5. The rejection of claims 22 and 85 under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial utility or a well-established utility is withdrawn in view of Applicant's arguments.
6. The rejection of claims 22 and 85 under 35 U.S.C. 112, first paragraph, NEW MATTER, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is withdrawn in view of the Applicant's amendment to claim 22.

***Response to Arguments***

7. The rejection of claims 22 and 85 under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is maintained.

The response filed 7/15/2004 has been carefully considered, but is deemed not to be persuasive. Applicants argue that, as discussed in section I of the response at page 7, the specification teaches that an antibody could be used to detect the expression of OLD-35 toward determining whether a cell is senescent, terminally differentiated, or growth arrested. This argument is not persuasive as there is no evidence of record that aberrations of cellular senescence, such as that found in a disorder such as cancer, are correlative with the expression of the OLD-35 protein. The specification does not exemplify any method (i.e., diagnostic or therapeutic), or describe any particular cancerous condition in which the monitoring of OLD-35 protein expression will provide information as to the status of the particular cancer. Thus, it would require further experimentation by the skilled artisan to characterize the regulation of OLD-35 protein expression during the disease process as well as during chemotherapy to ascertain whether monitoring the expression of the OLD-35 protein is indicative of the effectiveness of the chemotherapy, for example. Further, there is no evidence of record or teachings in the specification, as to how to distinguish among cells, which are growth arrested, terminally differentiated or senescent based on the detection of the OLD-35 protein. The

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response also argues that mRNA is validly correlated with protein expression and Figure 14 demonstrates that a nucleic acid comprising OLD-35 and GFP was translated to form a fluorescent protein and Applicant points to Lesczyniecka et al, which shows that GST-hPNPase<sup>OLD-35</sup> having PNPase activity could be expressed. In response to this argument, Figure 14 and Lesczyniecka et al do not teach any correlation between the level of mRNA expression and the level of protein expression or how the level of mRNA expression is predictive of the levels of protein expression. Further, Figure 14 and the art of Lesczyniecka et al do not teach any correlation between an altered expression level of the OLD-35 protein and a specific disease state such as cancer, for example. Further, the response did not address the art of Fu et al, Powell et al, Vallejo et al, Lewin and Jang et al and as evidenced by the art of art of Fu et al, Powell et al, Vallejo et al, Lewin and Jang et al, the skilled artisan cannot anticipate that the level of a specific mRNA expressed by a cell will be paralleled at the protein level due to the complex homeostatic factors controlling translation and post-translational modification. The response also argues that the specification at page 17 provides guidance to assist the skilled artisan on how to make and use antibodies to OLD proteins. In response to this argument, the specification at page 17 does teach how to make antibodies against the OLD-35 protein, however, the skilled artisan would not know how to use antibodies that bind the OLD-35 protein because Applicant has not provided any objective evidence of OLD-35 protein expression (i.e., ELISA or Western blot) correlated with a specific disease state or condition such that detection of OLD-35 would be indicative of

disease progression or regression. Therefore absent objective evidence correlating the level of protein expression of OLD-35 and a specific cancerous or disease state, the skilled artisan would not know how to use the claimed antibodies in a diagnostic or therapeutic setting without undue experimentation.

### ***Conclusions***

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER